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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)			
	10/690,472	SHACHAR, YEHOSHUA			
Office Action Summary	Examiner	Art Unit			
•	James Kish	3737			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
 Responsive to communication(s) filed on <u>18 October 2006</u>. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 					
Disposition of Claims					
4) Claim(s) 1-44 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-44 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or Application Papers 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) according a cordinate may not request that any objection to the Replacement drawing sheet(s) including the correct to the second and sheet are corrected to by the Examine and sheet are corrected to by the Examine are corrected to be corrected to by the Examine are corrected to be correc	vn from consideration. r election requirement. r. epted or b) objected to by the drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/18/06.	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate			

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DETAILED ACTION

Response to Arguments

Applicant's arguments filed October 18, 2006 have been fully considered but they are not persuasive.

- 1. With respect to Applicant's argument regarding Blume et al. (US Patent App. No. 2001/0021805) as not teaching or suggesting sensors to sense the location of the implant, the Examiner respectfully disagrees. Paragraph 39 explicitly states that "a magnetic locating device may be used or determining and displaying a position and orientation of implanted seed 30." This is further described in US Patent 5,558,091, issued to Acker et al. and is incorporated by reference in its entirety. See section 2163.07(b) of the MPEP where it is stated, "The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed."
- 2. With respect to Applicant's argument regarding McEwan (US Patent No. 6,914,552) as not being capable of sensing an object that is not vibrating, Examiner finds this argument moot in view of the Applicant's disclosure as stating, "One embodiment includes a catheter guidance and control apparatus... that is capable of producing a vibratory or pulsating motion of the tip with adjustable frequency and amplitude..." Also, as stated in the abstract of McEwan, "A varying magnetic field excites slight vibrations in an object..." Therefore, with the changing magnetic field needed to guide the implanted device, there would inevitably be slight vibrations

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present. Regarding Applicant's argument that McEwan does not teach or suggest piezoelectric rings, see paragraph 5 of this Office Action.

- 3. With respect to Applicant's argument that Blume in combination with McEwan does not teach the newly added limitations of claim 1, Examiner respectfully disagrees. As disclosed in Blume, "a computer calculates orientations and currents for an external electromagnet to move the implanted magnetic object in the patient's body through a desired path (see Abstract).
- 4. With respect to Applicant's argument that Hastings (US Patent No. 6,148,823) teaches a "C" magnet having two poles, but not a first and second plurality of poles, Examiner cites *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). "The court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced." See MPEP 2144.04.
- 5. With respect to Applicant's argument that Colley et al. (US Patent No. 4,354,501) does not teach or suggest using ultrasonic energy to locate a catheter tip, Examiner finds this argument moot in that the claimed limitation reads, "one or more piezoelectric rings disposed about said distal end" which is present in the Colley reference.
- 6. With respect to Applicant's argument that Kawashima (US Patent No. 4,292,961) does not provide sufficient capability to locate the longitudinal or other position aspects of the distal end within the body, Examiner has previously included McEwan in the rejection of claims 9-11 to make up for these deficiencies.
- 7. With respect to Applicant's argument that Blume et al. (US Patent No. 6,014,580) does not teach a virtual tip as described by the Applicant, the claims merely call for a

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virtual tip, which is provided for in Blume'580. Examiner stated in the Office Action dated May 15, 2006, at page 7, "While there is no mention of providing force feedback, it is well known in the art to incorporate feedback to virtual devices being used to guide medical procedures."

- 8. With respect to Applicant's argument that Green (US Patent No. 5,808,665) does not teach or suggest tactile feedback to an operator according to a position error between an actual position of said distal end and a desired position of said distal end, Examiner respectfully disagrees. Applicant agrees that Green provides feedback information from sensors by direct measurement. When in surgery, if the distal end of the probe (i.e. the actual position) comes into contact with the wall of a blood vessel the sensors will provide feedback to warn/redirect the surgeon to move the tip away from the wall (i.e. to a desired position).
- 9. With respect to Applicant's argument that Galel teaches controlling force at the proximal end of the catheter, nor at the distal end, Examiner points out that "the motion command received by a steering system... located at the proximal end of the catheter but actuate a steering mechanism at the distal end (column 4, line 67 through column 5, line 4)." By moving the proximal end, the distal end is steered simultaneously.
- 10. Examiner believes that paragraphs 1-9 of this Office Action clearly point out the attributes, which are argued to be deficient by the Applicant. Therefore, Applicant's argument that Hunter et al. (US Patent No. 6,381,485) does not teach or suggest these missing elements is moot.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-2, 8-12, 14, 17-20, 22, 25-27, 29-36, and 38-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-9, 11, 17-18, 21-23, 25-32, and 34-38 of copending Application No. 10/621,196. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions share an identical scope while only minor limitations exist within the claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1, 3-8, 14, 16, 21, and 25-32 are rejected under 35 U.S.C. 103(a) as 12. being unpatentable over Blume et al. 805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552). Blume'805 discloses a method and apparatus for displaying and using a shaped field of a repositionable magnet to move, guide, and/or steer a magnetic catheter in living tissue. Blume'805 provides a program that instructs a processor to calculate, from localizer inputs that result from fiducial markers, the location and orientation of a magnet to provide the magnetic field. Navigation can occur automatically or manually. Manual navigation would use inputs such as a keyboard, mouse, joystick, or any other input device or devices communicating with the processor (Paragraph [0037]). Also see Paragraph [0015] with respect to fiducial markers, as well as Paragraph [0034]. Paragraph [0039] discusses using fiducial markers in conjunction with CAT, X-ray, or MR images. With regard to claim 4, Paragraph 42 discloses more than one magnet/magnet assemblies can be used. While not directly stated, the processor is capable of being programmed to calculate a position error and automatically correct for said error. Fluoroscopic imaging is described in Paragraph

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[0043]. With regard to claim 8, item 42 of Figure 1 shows an operator interface. In regards to claim 14, the system is considered to have an X, Y and Z-axis controller and amplifier in order to appropriately position the catheter. While Blume'805 discusses locating the implanted medical device, there is no mention of doing so via radar. However, McEwan teaches a magneto-radar detector in which a radar detector picks up on slight vibrations of a device being tracked. One embodiment of this system utilizes an ultra-wideband micro power impulse radar (see Abstract). McEwan teaches that the second harmonic is generally the dominant frequency of interest (column 4, lines 6-8). With regard to claim 16, phased arrays are well known in the art (see Conclusion) and it would have been obvious to use such a radar system to permit rapid scanning and abrupt alignment changes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the navigation system of Blume'805 to use a radar system as taught by McEwan because this radar system can potentially track the location of a catheter inserted within a patient undergoing a medical procedure (column 2, lines 27-30).

13. Claims 35, 37-38 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552). Hastings discloses an apparatus for magnetically controlling a medical tool being inserted into a patient (Figure 5 and column 4, lines 41-50). A magnetic source is provided in, what can be considered, a cluster-like arrangement on a C-arm, as seen in Figure 1. Column

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5, lines 9-11 discusses an external controller used to guide the magnetic field. The controller is capable of changing the current to control the strength of the field. The Carm can rotate as described in column 5, lines 39-48. It is reasonable to use any medical device necessary for the given operation to be performed. Therefore, Colley teaches an example of a catheter that includes a piezoelectric ring being used to detect air emboli. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a tool with a piezoelectric ring at the distal end in order to detect air emboli in the use of the apparatus disclosed by Hastings. Neither Hastings nor Colley discuss a radar system to locate the distal tip. However, McEwan teaches a magneto-radar detector in which a radar detector picks up on slight vibrations of a device being tracked. One embodiment of this system utilizes an ultra-wideband micro power impulse radar (see Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the navigation system of Blume'805 to use a radar system as taught by McEwan because this radar system can potentially track the location of a catheter inserted within a patient undergoing a medical procedure (column 2, lines 27-30).

14. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Galel (US Patent No. 5,492,131). While Blume'805 discloses a servo system, there is no discussion of it being a closed-loop servo system. Galel teaches a closed-loop servo system being used to automatically navigate a

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catheter through a patient. Also, closed-loop feedback servo systems are well known in the art and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the well-known closed-loop servo system as taught by Galel in the system disclosed by Blume'805 in order to automate the navigation of the catheter.

15. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. 805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Kawashima (US Patent No. 4,292,961). Blume'805 discloses a magnetically navigable catheter system. When programmed correctly, the processor is capable of automatically compensating for the dynamic position of an organ with the aid of an auxiliary device (such as X-ray; Paragraph [0043]) and a radar system, while also; the manual input is capable of compensating for such motion. However, Kawashima teaches an apparatus for automatically controlling the position of a device within a cavity. A control mechanism automatically controls the position of the distal portion of the device in the cavity (column 1, lines 56-60). While Kawashima accomplishes the automatic position correction without the use of auxiliary devices, the end result of positioning the distal end of the device with respect to the surrounding cavity/organ is the same and therefore, Kawashima is sited as a function equivalent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate automatic position compensation as taught by Kawashima so

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that no particular skill is required for the insertion of the device into a cavity to allow the device to become available for more frequent use (column 2, lines 4-11).

- Claims 12-13, 17, 20, 34 are rejected under 35 U.S.C. 103(a) as being 16. unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Blume et al. 580 (US Patent No. 6,014,580). Blume'805 discloses a magnetically navigable catheter system. However, the input devices disclosed do not include a virtual tip. However, Blume'580 teaches a "virtual catheter" used in place of a joystick supplied with a shape similar to an actual magnetic tipped catheter being used for a surgical procedure (column 8, lines 7-19). While there is no mention of providing force feedback, it is well known in the art to incorporate feedback to virtual devices being used to guide medical procedures. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a virtual tip as taught by Blume'580 to guide the actual catheter. Signals corresponding to the bending of the virtual tip could be sent to the processor, which would then convert the bending to corresponding magnetic fields to be applied to the actual tip that would result in the actual catheter being directed in the surgical procedure in a direction corresponding to the bending of the virtual catheter.
- 17. Claims 18-19, 22, 24, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al.'805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Blume et al.'580 (US Patent No.

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6,014,580), in even further view of Green (US Patent No. 5,808,665). Blume'805 and Blume'580 combine to create a catheter magnetically navigable with a virtual catheter. However, tactile feedback to the input device is not mentioned. Green teaches tactile feedback being used in virtual surgical instruments to give the operator more realism (column 11, lines 9-29). It would have been obvious t one having ordinary skill in the art at the time the invention was made to have included tactile feedback, as taught by Green, in the virtual catheter, as disclosed by Blume, in order to provide the operator with the realism necessary to perform surgery.

18. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552), in even further view of Galel (US Patent No. 5,492,131). Hastings, Colley and McEwan, as combined in the rejection of claim 35 above, discloses an apparatus for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. However, the system is not disclosed as a closed-loop servo system. Galel teaches a closed-loop servo system being used to automatically navigate a catheter through a patient. Also, closed-loop feedback servo systems are well known in the art and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the well-known closed-loop servo system as taught by Galel in the system disclosed by Hastings in order to automate the navigation of the catheter.

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Claims 39-41 is rejected under 35 U.S.C. 103(a) as being unpatentable over 19. Hastings (US Patent No. 6,148,823) as modified by Colley et al. (US Patent No. 4,354,501), McEwan (US Patent No. 6,914,552) and Galel (US Patent No. 5,492,131) as combined in the rejection of claim 36 above, further in view of Blume'805 and Kawashima. Hastings, Colley, McEwan and Galel disclose a closed-loop servo system for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. Blume'805 discloses a magnetically navigable catheter system. When programmed correctly, the processor is capable of automatically compensating for the dynamic position of an organ with the aid of an auxiliary device (such as X-ray; Paragraph [0043]) and a radar system, while also; the manual input is capable of compensating for such motion. However, Kawashima teaches an apparatus for automatically controlling the position of a device within a cavity. A control mechanism automatically controls the position of the distal portion of the device in the cavity (column 1, lines 56-60). While Kawashima accomplishes the automatic position correction without the use of auxiliary devices, the end result of positioning the distal end of the device with respect to the surrounding cavity/organ is the same and therefore, Kawashima is sited as a function equivalent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have configured the magnet source of Blume as modified by Kawashima on a C-arm as taught by Hastings in order to provide a stronger field for a given magnet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the navigation system of Blume'805 to use a

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radar system as taught by McEwan because this radar system can potentially track the location of a catheter inserted within a patient undergoing a medical procedure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a tool having piezoelectric rings at the distal end as taught by Colley in the apparatus of Blume as modified by Kawashima in order to detect air emboli in a possible application of the apparatus of Hastings. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a well-known closed-loop feedback servo system as taught by Galel as the type of servo system in Blume as modified by Kawashima in order to provide automated advancement and positioning.

20. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552), in even further view of Blume'580. Hastings, Colley and McEwan, as combined in the rejection of claim 35 above, discloses an apparatus for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. However, the input devices disclosed do not include a virtual tip. However, Blume'580 teaches a "virtual catheter" used in place of a joystick supplied with a shape similar to an actual magnetic tipped catheter being used for a surgical procedure (column 8, lines 7-19). While there is no mention of providing force feedback, it is well known in the art to incorporate feedback to virtual devices being used to guide medical procedures. Therefore, it would have

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been obvious to one having ordinary skill in the art at the time the invention was made to utilize a virtual tip as taught by Blume'580 to guide the actual catheter. Signals corresponding to the bending of the virtual tip could be sent to the processor, which would then convert the bending to corresponding magnetic fields to be applied to the actual tip that would result in the actual catheter being directed in the surgical procedure in a direction corresponding to the bending of the virtual catheter.

21. Claims 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. 805 (US Application No. 2001/0021805) in view of McEwan (US Patent No. 6,914,552), further in view of Hunter et al. (US Patent No. 6,381,485).

Blume 805 and McEwan, as combined in the rejection of claims 1, 3-8, 14, 16, 25-29, and 31-32 above, discloses an apparatus for magnetically controlling a medical device. However, the fiducial sensors that are used are not disclosed as 6-DOF sensors.

Hunter teaches 6-DOF sensors used to register fiducial marker location and orientation between image space and patient space. By registering the medical device in patient space with the aid of the 6-DOF sensors, the processor is capable of being programmed to use this information, as well as the information from the radar system, to correct position errors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use 6-DOF sensors as taught by Hunter to register the images taken by the auxiliary device with the actual image space.

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22. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings (US Patent No. 6,148,823) in view of Colley et al. (US Patent No. 4,354,501), further in view of McEwan (US Patent No. 6,914,552), further in view of Hunter et al. (US Patent No. 6,381,485). Hastings, Colley, and McEwan disclose a closed-loop servo system for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system. However, the fiducial sensors that are used are not disclosed as 6-DOF sensors. Hunter teaches 6-DOF sensors used to register fiducial marker location and orientation between image space and patient space. By registering the medical device in patient space with the aid of the 6-DOF sensors, the processor is capable of being programmed to use this information, as well as the information from the radar system, to correct position errors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use 6-DOF sensors as taught by Hunter to register the images taken by the auxiliary device with the actual image space.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on $8:30 - 5:00 \sim Mon. - Fri..$

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER

JMK